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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|------------------------------|------------------|
| 10/768,194 | 02/02/2004 | Douglas Hovey | 029318-1001 | 3657 |
| 31049 7590 01/29/2007 ELAN DRUG DELIVERY, INC. C/O FOLEY & LARDNER LLP 3000 K STREET, N.W. SUITE 500 WASHINGTON, DC 20007-5109 | | | EXAMINER GEORGE, KONATA M | |
| | | | ART UNIT 1616 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS | | MAIL DATE 01/29/2007 | DELIVERY MODE PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/768,194

Applicant(s)

HOVEY ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16, 17, 19-35, 39-54, 59-76 and 81 is/are rejected.
- 7) ☒ Claim(s) 13-15, 35-37, 55-58 and 77-80 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/3/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claims 1-17 and 19-99 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on November 3, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the examiner has considered the information disclosure statement.

Action Summary

2. The objections of claims 3, 13, 35, 56, 70 and 78 are hereby withdrawn.

3. The rejection of claims 17, 20 and 21 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn.

4. The rejection of claims 1, 2, 4, 5, 10, 12, 39-41, 44, 48, 53, 54 and 70 under 35 U.S.C. 102(3) as being anticipated by Wertz et al. is being maintained for the reasons stated in the previous office action.

5. The rejection of claims 1-11, 16, 39-45, 47-54, 59-62, 64-76 and 81 under 35 U.S.C. 103(a) over Karlsson et al. is being maintained for the reasons stated in the previous office action.

6. The rejection of claims 17, 19-38, 46 and 63 under 35 U.S.C. 103(a) over Karlsson et al. is being maintained for the reasons stated in the previous office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 4, 5, 10, 12, 39-41, 44, 48, 53, 54 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Wertz et al. (US 2003/0185869).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

It is noted by the examiner that the filing date of the prior art is the same as the date of the provisional application of the instant invention. Examiner is relying on the provisional date of the provisional application of the prior art, which claims the same invention and has a date February 4, 2002.

Example 8, ¶ [0161-0164] teach a method of producing fluticasone propionate particles utilizing lysozyme as a surface stabilizer. The particles are produced by a

Art Unit: 1616

milling process, which produces fluticasone propionate particles having a mean particles size of 311 nm.

Declaration Under 37 C.F.R. § 1.132

8. The Declaration under 37 CFR 1.132 filed August 7, 2006 is insufficient to overcome the rejection of claims 1, 2, 4, 5, 10, 12, 39-41, 44, 48, 53, 54 and 70 based upon 35 U.S.C. 102(e) as set forth in the last Office action because: Applicant has not signed the declaration, therefore, it has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-11, 16, 17, 19-35, 39-54, 59-76 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson et al. (US 2002/0065256 A1).

Karlsson et al. discloses a process for sterilization of a powdered form of a glucocorticosteroid wherein the glucocorticosteroids are used in the treatment of allergic and/or inflammatory conditions of the nose or lungs (abstract). ¶ [0016] teach examples of the glucocorticosteroid used in the composition i.e. fluticasone (e.g. as propionate). ¶ [0017] teach the particle size as less than 10 microns. ¶ [0031] teach the use of the composition. ¶ [0033] teaches the use of pharmaceutically acceptable additives. ¶

Art Unit: 1616

[0035] teach suitable surfactants that can be employed in the composition, mention being made to Tyloxapol™ and polyoxyethylene alkyl ethers. ¶ [0036] teach the concentration of the surfactant at about 0.002 to 2% w/w. ¶ [0042] teach the percentage of particles having a specific particle size. ¶ [0044] teach that a suspension containing the active agent and additional ingredients can be produced by sterile filtration. The several examples teach the active agent in concentrations as claimed by applicant. The prior art does not teach specific examples using fluticasone as claimed by applicant.

It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the cited glucocorticosteroids in the instant invention. As paragraph [0016] teaches examples of glucocorticosteroids one of ordinary skill could substitute any one of the glucocorticosteroids listed (i.e. fluticasone) to achieve the same desired results of treating allergic and/or inflammatory condition of the nose or lungs (e.g. chronic obstructive pulmonary disease, asthma, etc.).

Response to Arguments

10. Applicant's arguments filed August 7, 2006 have been fully considered but they are not persuasive.

Applicants argue that Karlsson does not provide motivation to make a composition having a drug particles size in which 50% of the particles are less than 1 micron, as Karlsson is directed to particles having much larger sizes. The examiner

Art Unit: 1616

disagrees. As stated in the previous office action the particles of Karlsson can have a mass median diameter of less than 1 micron [0017] and the claimed invention claim particle size of less than 900 nm, which fall into the range of less than 1 micron and is thus obvious. Applicant argues that the 1 micron particle of Karlsson fall within the bottom range of the particle size range. Although the particle size of Karlsson is in the bottom range, the size range still overlaps. Therefore, the range reads on the claimed composition range and the characteristics of the composition would be the same. Applicant merely claims a composition of particles having a particular particle size and a surface stabilizer. Therefore, any composition having the particle size and stabilizer reads on the instant invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 82-99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has added claims 82-99 to the instant invention. These claims are directed towards a composition comprising solid particles of an agent coated with one or more surface modifiers. The specification does

Art Unit: 1616

not disclose coating solid particles of an immunosuppressive agent with a surface modifier. There is no disclosure of coating any type of particles in the specification.

This is considered new matter and is thus rejected.

Conclusion

12. Claims 1-11, 16, 17, 19-35, 39-54, 59-76 and 81 are rejected.
13. Claims 13-15, 35-37, 55-58 and 77-80 are objected too. The prior art of Karlsson et al. does not teach the cationic surface stabilizer as claimed by applicant.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

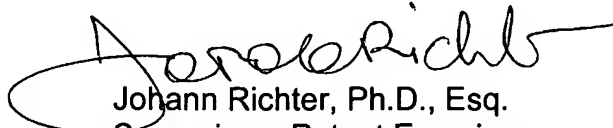
Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Patent Examiner
Technology Center 1600


Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600